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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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EXAMINER

KISHORE . G

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/21/00

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 6-13-00

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 - month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-13 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1-13 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

—SEE OFFICE ACTION ON THE FOLLOWING PAGES—

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DETAILED ACTION

The amendment with attachment dated 6-13-00 is acknowledged.

Claims included in the prosecution are 1-13.

Claim Rejections - 35 U.S.C. § 112

- 1. The following is a quotation of the second paragraph of 35 U.S.C. 112:**

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Applicants amend claim 1 to recite 'consisting essentially of'. Such a limitation requires that the specific components be recited and does not permit the addition of any compound or component which affects the novel characteristics of the composition. Instant dependent claims recite additional ingredients which appear to be essential components which affect the basic nature of the composition.

The distinction between 'water insoluble compound' on line 2 of claim 1 and 'water insoluble particulate solid on line 4 is unclear.

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The distinction between ‘phospholipid’ and ‘amphipathic surfactant’ in claim 2 is unclear. Phospholipids are amphipathic surfactants. Applicants have not addressed this issue.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

4. Claims 1-4, 6 and 8-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Green (5,976,577).

Green discloses rapidly dispersing oral dosage forms wherein the particles are coated with claimed components, The composition contains, other claimed components (note the abstract, columns 5-8, Examples and claims).

Applicants’ arguments have been fully considered, but are not found to be persuasive. Applicants argue that Green’s particles are coarse particles, for e.g., 75

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micrometers to 400 micrometers, more usually in the region of 100-300 micrometers. This argument is not found to be persuasive since independent claim does not set forth any specific size range. Furthermore, according to claim 1, the nanometer and micrometer sizes are for the water insoluble compounds and not for the total particle and according to claim 2, it is the size of the water insoluble particle and not the total particle. The sizes in Green are the sizes of the particles after coating. Applicants' arguments with regard to coating process which is apparently different from that of Green are not found to be persuasive since instant claims are not process claims. Green teaches micrometer range rapidly disintegrating particles coated with a phospholipid and which dissolve in less than 10 seconds (note col. 3, lines 48-49 and claims 8 and 10 and thus, the reference meets the requirements of instant claims.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green cited above, further in view of Libby (4,432,975).

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Green does not teach the inclusion of polyethylene glycol in the formulations. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to include polyethylene glycol in the quick disintegrating formulations of Green with the expectation of obtaining at least similar results since the reference of Libby shows the common practice in the art of inclusion of this compound in quick disintegrating formulations (note the abstract and col. 3).

Applicants provide no specific arguments with regard to this rejection. The rejection therefore, is maintained.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Green cited above, further in view of Carli (5,164,380).

Green does not teach the inclusion of colloidal silica in the formulations. In the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to include colloidal silica in the quick disintegrating formulations of Green with the expectation of obtaining at least similar results since the reference of Carli shows the common practice in the art of inclusion of this compound in quick disintegrating formulations (note the abstract and Example 4).

Applicants provide no specific arguments with regard to this rejection. The rejection therefore, is maintained.

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8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

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Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

August 20, 2000